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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,606	10/16/2001	Barry E. Rothenberg	24065-004CON	6347

7590 09/11/2003  
MINTZ, LEVIN, COHN, FERRIS,  
GLOVSKY and POPEO, P.C.  
One Financial Center  
Boston, MA 02111

EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 09/11/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding:

**Office Action Summary**

Application No.

09/981,606

Applicant(s)

ROTHENBERG ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2 and 59-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 59-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's preliminary amendment filed in Paper No. 17 is acknowledged. Claims 3-58 have been cancelled. Claim 1 has been amended. Claims 59-67 have been added. It is noted that claim 2 is missing from the preliminary amendment. In Applicant's remarks, only claims 1 and 59-67 are listed as pending. However, no amendment has been filed wherein claim 2 has been canceled. Therefore, claims 1, 2 and 59-67 are pending in the instant application.

### ***Specification***

2. The disclosure is objected to because of the following informalities:

(a) The priority document is not listed in the first sentence on the first page of the specification (see 37 CFR 1.78(a) and MPEP 201.11). It is suggested amending the disclosure to recite the priority information in the first sentence of the specification.

(b) The use of the trademark "Taqman" at page 17, line 24 has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1, 2, 59-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1, 2 and 59-67 are indefinite at the recitation of "HFE" in claim 1 because abbreviations often have more than one meaning in the art. Accordingly, it is suggested amending the claim to recite the full name of the abbreviation as recited in the specification as originally filed.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 2 and 59 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 11 of U.S. Patent No. 6, 355,425 B1.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claims(s). See, e.g. *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226

(Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Here, claim 1 recites a method of diagnosing an iron disorder or a genetic susceptibility to developing said disorder in a mammal, comprising determining the presence of a mutation in exon 2 of an HFE nucleic acid in a biological sample from said mammal, wherein said mutation is not a C to G substitution at nucleotide 187 of SEQ ID NO: 1 and wherein the presence of said mutation is indicative of said disorder or a genetic susceptibility to developing said disorder. Claim 2 recites the embodiment of claim 1 wherein said disorder is hemochromatosis and claim 11 recites an embodiment of claim 1, wherein said mutation is at nucleotide 193 of SEQ ID NO: 1. The method of claims 1, 2 and 11 differs from the claims 1, 2 and 59 of the instant invention in that they fail to disclose wherein said determining step is carried out by nucleic acid hybridization on a microchip. However, the portion of US Patent 6,355,425 B1 that supports the use of hybridization on a microchip to detect a mutation teaches the use of a number of nucleic acid based assay for HFE mutations. The patent '425 B1 specifically discloses wherein the mutation is detected by using standard sequencing assay, nucleic acid hybridization, e.g., using standard Southern, Northern or dot blot hybridization assay systems. The patent further discloses that nucleic acid hybridization assays are also carried out using a bioelectronic microchip technology known in the art. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate hybridization on a microchip array as known in the art to detect the presence of a mutation in a desired sample. One having ordinary skill in the art would have been motivate to incorporate the hybridization assay in the method based on the supporting portions of US patent 6,355,425 B1.

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***Conclusion***

7. No claims are allowed. However the claims are free of the prior art because the prior art does not teach or suggest a method of diagnosing an iron disorder or a genetic susceptibility to developing said disorder in a mammal comprising determining the presence of a mutation in exon 2 of an HFE nucleic acid, wherein said mutation is at position 193 of SEQ ID NO: 1 and is not a C to G substitution at nucleotide 187 of SEQ ID NO: 1 and wherein the presence of said mutation is indicative of said disorder or a genetic susceptibility to developing said disorder.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308 0196.

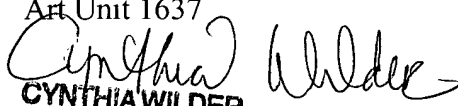
cbw

September 10, 2003

Cynthia B. Wilder, Ph.D.

Examiner

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**CYNTHIA WILDER**  
**PATENT EXAMINER**